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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,233	07/25/2001	Samuel J. Tremont	061765.00195	4337

22907 7590 08/11/2004

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WASHINGTON, DC 20001

EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

Office Action Summary**Application No.**

09/912,233

Applicant(s)

TREMONT ET AL.

Examiner

Brenda Coleman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-162,167,188 and 205-265 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-162,167,188 and 205-265 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-162, 167, 188 and 205-265 are pending in the application.

This action is in response to applicants' amendment dated May 25, 2004. Claims 1-3, 8-10, 14, 29- 31, 36-39, 75-77, 82-85, 88, 121, 122, 125, 141, 142, 145, 167, 188, 205 and 237 have been amended.

Note: The applicants' are reminded of the manner of making amendments.

37 CFR 1.121 Manner of making amendments in application.

(c) Claims. Amendment to a claim must be made by rewriting the entire claim with all changes (e.g., additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an exiting claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims in the amendment document will serve to replace all prior versions of the claims in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).

The following claims fail to properly identify the status of the claims:

claims 39, 42, 85, 128, 148, 188, 211, 230, 241, 253, 255, 256 and 262-265.

Response to Amendment

Applicant's amendments filed May 25, 2004 have been fully considered with the following effect:

1. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejection labeled o) maintained in the last office action which is hereby **withdrawn**.

2. With regards to the 35 U.S.C. § 112, first paragraph rejection of claims 1-9, 14-37, 42-83, 88-124, 128-144, 148-162, 167, 188, 205-225, 250-253, 256-260 and 263 labeled paragraph 2) of the last office action, the applicant's arguments have been fully considered but are not found persuasive with respect to claim 167. The applicants stated that they have amended claims 1-3, 8, 9, 29-31, 36, 37, 75-77, 82, 83, 121, 122, 141, 142 and 205 to delete the clause containing “-N⁺R⁹R¹¹R¹²A-” as the noted substituent. However, claim 167, which was included in the rejection, has not been amended. See page 123 of 167.

Claims 167, 253 and 260 are rejected under 35 U.S.C. 5 1 12, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record and stated above.

3. With regards to the 35 U.S.C. § 112, second paragraph rejection labeled paragraph 4b) and c) of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive.

b-c) The applicant's stated that they have amended claim 9 to delete this matter and thereby correct these typographical errors. The slash marks which the applicants stated were deleted by way of the slash/hyphen where the slash crosses over the hyphen should not have been present in this amended, since all

deleted subject matter in the previous amendment should not appear in the current claims. However, they are still present. See page 20 of 167.

Claims 9, 250, 256 and 257 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

4. The applicant's amendments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 6) of the last office action, which is hereby **withdrawn**.

5. The applicant's amendments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 7a), b), c), h), i), j), k) and l) of the last office action, which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejections labeled d), e), f) and g) of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive.

d) The applicants stated that the term "OM" has been replaced by "-OM". However, this is not so for claims 29 and 188. See pages 33 and 129 of 167.

Claims 29-55, 59-71, 188, 250, 253, 256, 257 and 260 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

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e) The applicants stated that the term $-PR^{13}R^{14}$ had been split across two lines. Since the point of attachment existed, a hard return was simply used to put the whole term together. However, $-PR^{13}R^{14}$ which is a divalent moiety doesn't indicate the second point attachment. See pages 6, 33, 62, 124, 129 and 135 of 167.

Claims 1-25, 29-55, 59-71, 75-101, 105-117, 167, 188, 205-222, 250, 253, 256, 257, 260 and 263 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

f) The applicants stated that the claims have been amended to replace the term " $N^+R^9R^{10}A^-$ " with " $N^+R^9R^{10}A^-$ ". However, this is not so for claim 85. See pages 79 of 167.

Claims 85, 250, 256 and 257 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

g) The applicants stated that this rejection is not understood. The rejection is on the basis that it is not apparent that at any time can $-OR^9$ be substituted with the moiety $-O(CH_2)_{1-4}N^+R'R''R'''A^-$. See pages 34 and 63 of 167.

Claims 29-120, 250, 256 and 257 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

In view of the amendment dated May 25, 2004, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 1-25, 29-120, 125-127, 135-140, 145-147, 155-160, 167, 188, 205-225, 250-254, 256-260 and 263-265 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reason(s) apply:

a) Claims 1-25, 29-55, 59-71, 75-101, 105-117, 205-225, 250, 253, 256, 257, 260 and 263 are vague and indefinite in that it is not known what is meant by the moiety NO₂, which is the only moiety in the definition of the substituents on the R¹⁸ alkyl; alkenyl; alkynyl; aryl; heterocyclyl; quaternary heterocyclyl; arylalkyl; heterocyclylalkyl; acyl; alkoxycarbonyl; arylalkoxycarbonyl; and heterocyclylalkoxycarbonyl; that doesn't indicate the point of attachment. See pages 6, 34, 63 and 135 of 167.

- b) Claim 6, 8, 34, 36, 80 and 82 are vague and indefinite in that the semicolon after the definition of R^3 is part of a superscript. See pages 17, 43, 44 and 73 of 167.
- c) Claims 10-13, 250, 256 and 257 recite the limitation "carboxyalkylheterocyclyl" in the definition of R^9 and R^{10} . There is insufficient antecedent basis for this limitation in the claim. See page 23 of 167.
- d) Claims 11, 250, 256 and 257 recite the limitation "carboxyalkylheterocyclyl" in the definition of R^9 and R^{10} . There is insufficient antecedent basis for this limitation in the claim. See page 23 of 167.
- e) Claims 38, 40-74, 250, 256 and 257 recite the limitation "carboxyalkylheterocyclyl" in the definition of R^9 and R^{10} . There is insufficient antecedent basis for this limitation in the claim. See page 49 of 167.
- f) Claims 39, 85, 250, 256 and 257 recite the limitation "wherein alkyl optionally has one or more carbons replaced by O or $N^+R^9R^{10}A^-$ " in the definition of R^{19} . There is insufficient antecedent basis for this limitation in the claim. See page 50 and 79 of 167.
- g) Claims 39, 250, 256 and 257 recite the limitation "carboxyalkylheterocyclyl" in the definition of R^9 and R^{10} . There is insufficient antecedent basis for this limitation in the claim. See page 50 of 167.
- h) Claims 84-120, 250, 256 and 257 recite the limitation "carboxyalkylheterocyclyl" in the definition of R^9 and R^{10} . There is insufficient antecedent basis for this limitation in the claim. See page 79 of 167.

- i) Claims 85, 250, 256 and 257 recite the limitation "carboxyalkylheterocyclyl" in the definition of R^9 and R^{10} . There is insufficient antecedent basis for this limitation in the claim. See page 79 of 167.
- j) Claims 125-127, 135-140, 251 and 258 recite the limitation "carboxyalkylheterocyclyl" in the definition of R^9 and R^{10} . There is insufficient antecedent basis for this limitation in the claim. See page 98 of 167.
- k) Claims 145-147, 155-160, 252 and 259 recite the limitation "carboxyalkylheterocyclyl" in the definition of R^9 and R^{10} . There is insufficient antecedent basis for this limitation in the claim. See page 114 of 167.
- l) Claims 205-225, 254, 260 and 263 are vague and indefinite in that it is not known what is meant by the moiety llylaminoalkyl in the definition of R^{13} , R^{14} and R^{15} . See page 132 of 167.
- m) Claim 209 is vague and indefinite in that the semicolon after the definition of R^{30} is part of a superscript. See pages 137 of 167.
- n) Claim 263 is vague and indefinite in that it is not known what is meant by the moieties in line 3 on page 157 of 167 and in line 2 on page 158 of 167, which is lacking the carbonyl of the sugar.
- o) Claim 263 is vague and indefinite in that it is not known what is meant by the moieties in lines 4 and 5 on page 157 of 167, in lines 1, 3 and 4 on page 158 of 167 and in lines 1-3 on page 159 of 167, which is lacking the $-CH_2-OH$ of the sugar.

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p) Claim 264 is vague and indefinite in that it is not known what is meant by the moieties in line 3 on page 159 of 167 and in line 3 on page 160 of 167, which is lacking the carbonyl of the sugar.

q) Claim 264 is vague and indefinite in that it is not known what is meant by the moieties in line 4 on page 159 of 167, in lines 1, 2 and 4 on page 160 of 167 and in lines 1-4 on page 161 of 167, which is lacking the $-\text{CH}_2\text{-OH}$ of the sugar.

r) Claim 265 is vague and indefinite in that it is not known what is meant by the moieties in line 3 on page 161 of 167 and in line 4 on page 162 of 167, which is lacking the carbonyl of the sugar.

s) Claim 265 is vague and indefinite in that it is not known what is meant by the moieties in lines 1, 2, 3 and 5 on page 162 of 167 and in lines 1-4 on page 163 of 167, which is lacking the $-\text{CH}_2\text{-OH}$ of the sugar.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 141-143, 145, 146, 149, 151, 154, 155, 157, 160, 252 and 259 are rejected under 35 U.S.C. 102(b) as being anticipated by BRIEADDY et al., WO 94/18184. BRIEADDY teaches the compounds, compositions and method of use of the compounds of formula V where $\text{R}^{2\text{E}}$ is ethyl; $\text{R}^{2\text{F}}$ is n-butyl; R^{26} is H; R^{25} is methoxy; and

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R²⁷ is 4-hydroxyphenyl or 4-benzyloxyphenyl. See RN 163445-17-8; 163445-18-9; 163445-06-5; and 152802-50-1.

8. Claims 141-143, 149, 152, 252 and 259 are rejected under 35 U.S.C. 102(b) as being anticipated by BRIEADDY, WO 96/05188. BRIEADDY teaches the compounds, compositions and method of use of the compounds of formula V where R^{2E} is ethyl; R^{2F} n-butyl; R²⁵ is H; R²⁶ is methoxy; and R²⁷ is 4-fluorophenyl. See RN 178259-57-9.

9. Claims 141-146, 149, 151, 154, 155, 157, 160, 161, 252 and 259 are rejected under 35 U.S.C. 102(b) as being anticipated by BRIEADDY, WO 93/16055. BRIEADDY teaches the compounds, compositions and method of use of the compounds of formula V where R^{2E} and R^{2F} are ethyl; R²⁵ is H; R²⁶ is H; and R²⁷ is 4-methoxyphenyl, 4-methylphenyl, 4-chlorophenyl, 2-nitrophenyl, 4-nitrophenyl, 4-benzyloxyphenyl, 2-fluorophenyl, 3-fluorophenyl, 4-trifluoromethylphenyl, 3-trifluoromethylphenyl, 3,4-difluorophenyl, 2,4-difluorophenyl, etc. See RN 152802-39-6; 152802-40-9; 152802-41-0; 152802-43-2; 152802-46-5; 152802-47-6; 152802-48-7; 152802-49-8; 152802-50-1; 152802-51-2; 152802-53-4; 152802-54-5; 152802-55-6; 152802-58-9; 152802-59-0; 152802-60-3; 152802-61-4; etc.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 141-147, 149-162, 252 and 259 are rejected under 35 U.S.C. 103(a) as being unpatentable over BRIEADDY, WO 96/05188, WO 94/18184 and WO 93/16055. The generic structures of BRIEADDY encompass the instantly claimed compounds (see Formula I, page 2 of WO 96/05188) as claimed herein. The 5th species from the bottom of page 8 of WO 96/05188 anticipates the compounds, compositions and method of use of the compounds of formula V of the instant invention as outlined above in the 102 (b) rejection as do WO 94/18184 and 93/16055 above. This species differs only in the substituent R¹, R², R⁴, R⁶ and R⁷. Page 2 defines the substituents R¹ is a straight chained C₁₋₆ alkyl group; R² is a straight chained C₁₋₆ alkyl group; R⁴ is pyridyl or optionally substituted phenyl; and R⁶ and R⁷ are hydrogen, halogen, cyano, etc.. The compounds of the instant invention are generically embraced by BRIEADDY in view of the interchangeability of the substitutions of formula I. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example ethyl and n-butyl as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-162, 167, 188 and 205-265 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-263 of copending Application No. 10/333,842. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds, compositions and method of use of the compounds of formulae I, IA, IB, III, V, VII, VIIA, VIIB, VIII and IX are embraced by the compounds, compositions and method of use of the compounds of the formulae of 10/333,842.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Brenda Coleman

Primary Examiner Art Unit 1624

August 9, 2004